



United States Department of Agriculture

One Team, One Purpose



Food Safety and Inspection Service

Protecting Public Health and Preventing Foodborne Illness



Food Safety and Inspection Service:
Office of Policy & Program Development

The Approval Process for New Technologies & New Ingredients

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Food Safety and Inspection Service: *RIMS Innovations Programs*

❑ *RIMS works with other Offices in FSIS to:*

- Assess the use of new technologies and new ingredients to ensure they have a strong scientific basis, do not impede inspection procedures, will not cause harm to FSIS personnel and will meet regulatory requirements
- Evaluate suitability of substances for use on and in meat, poultry, and egg products (antimicrobials, processing aids, and ingredients)
- Develop programs to foster the development and implementation of new technologies to improve food safety

Food Safety and Inspection Service: *Overview*

☐ ***After this overview, you will become familiar with:***

- How we define a new technology & new ingredient
- Notification procedures – new technology & new ingredient
- Protocol requirements
- Waiver of regulations
- How to submit a protocol
- The review process
- Responsibilities of establishments regarding the validation of a new technology
- Where to find additional resources

Food Safety and Inspection Service:

What is a New Technology or New Ingredient?

❑ **Definitions:**

- For the purpose of FSIS, a new technology is defined as new or new applications of equipment, methods, processes, or procedures affecting the slaughter of livestock or poultry or processing of meat, poultry, or egg products
- A new ingredient is a substance that has no prior approval or has not been deemed acceptable for use in meat, poultry or egg products

Food Safety and Inspection Service: *Notification Procedures*

□ ***Notifications:***

- A notification is a document written to inform FSIS that a new technology is going to be used in an establishment. The notification should describe the purpose of the new technology and conditions of use

Food Safety and Inspection Service: *Protocol Requirements*

□ **Protocols:**

When FSIS reviews new technologies and new ingredients protocols we ensure that their will not adversely affect:

1. Product safety
2. Inspection procedures
3. Inspector safety
4. Agency regulations

Food Safety and Inspection Service: *Protocol Requirements*

□ **Protocols:**

- ***New Technology*** - A detailed plan of a scientific experiment, treatment, or procedure to test a new technology in a production environment . The plan should include the objectives and methods for conducting in-plants trials
- ***New Ingredient*** – A detailed plan of the function, proposed levels of use and safety of the ingredient. Per the MOU between FDA/FSIS, FDA determines safety of ingredients and FSIS determines efficacy/suitability

Food Safety and Inspection Service: *Product Safety*

☐ **Protocols:**

- Should describe the rationale as to why the new technology will not adversely affect the safety of products
- Indicate if the new technology or new ingredient results in adulteration of product or misleads consumers
- Include what the new technology or ingredient is intended to accomplish as well as the beneficial effects that the technology is expected to have on products

Food Safety and Inspection Service: *Inspection Procedures*

☐ **Protocols:**

- The protocol should describe the rationale as to why the technology will not interfere with FSIS inspection personnel from performing their inspection procedures

Food Safety and Inspection Service: *Safety of Inspection Program Personnel*

☐ **Protocols:**

- The protocol should describe the rationale as to why the technology will not affect or jeopardize the safety of FSIS inspection personnel
- Include a description of safety measures taken to ensure their safety
- Examples of safety measures include installation of shields , fans, new construction to isolate the technology, protective equipment and material safety data sheets (MSDS)

Food Safety and Inspection Service: *Regulations*

Protocols:

- The notification or protocol should cite any regulatory authority allowing use of the new technology or new ingredient
- Explain why the technology or ingredient does not violate any existing regulatory requirements
- The Agency does have the authority to waive provisions of the regulations to permit experimentation
- In-plant trials may be granted so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements

Food Safety and Inspection Service: *Granting Waivers of Regulations*

□ **Waivers:**

- FSIS regulations 9 CFR 303.1(h), 381.3(b), and 590.10 authorizes the Administrator to waive for limited periods any provisions of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements

Food Safety and Inspection Service: *Granting Waivers of Regulations*

□ **Waivers:**

- FSIS grants waivers of regulations when supported by sound data and rationale
- Allows alternative procedures in place of the waived portion of regulation
- Example - FSIS has granted a waiver to the Regulatory Requirements for Freezing Egg Products which specifically extends requirements from 60-96 hours 9 CFR 590.536 (a)

Food Safety and Inspection Service: *How to submit a protocol*

❑ ***Where to submit to:***

- Protocols for review can be submitted to
United States Department of Agriculture
Food Safety and Inspection Service
Risk, Innovations, and Management Staff
Patriots Plaza III, Cubicle 8-163A
1400 Independence Ave., SW.: STOP 3782
Washington, DC 20250-3700 or
Email: TPDS.protocols@usda.gov

Food Safety and Inspection Service: *Review Process*

□ **Review :**

- FSIS will put together a technical review team (TRT) to review the submission
- Takes up to 60 days. However it can take longer if additional information is needed
- Will dialogue with the company when necessary

Food Safety and Inspection Service: *Review Process*

□ **Review :**

- FSIS will issue a letter of no objection if the technology:
 - Does not adversely affect product safety
 - Interfere with FSIS inspection procedures
 - Jeopardize inspection personnel safety or
 - If the Agency granted a waiver of a regulation for the new technology

Food Safety and Inspection Service: *Review Process*

□ **Review :**

- New technologies that have been approved will be listed on our NT website
<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/New-Technologies>

Food Safety and Inspection Service: *Prior Approved Substances*

❑ ***Prior Approved Substances:***

- Prior approved substances are listed in [9 CFR 424.21\(c\)](#)

Food Safety and Inspection Service:
FSIS Directive 7120.1

❑ ***Directive 7120.1:***

- The [*Table of Safe and Suitable Ingredients*](#) and [*FSIS Directive 7120.1*](#), lists food grade substances that have been approved in 21 Code of Federal Regulations (CFR) for use in meat, poultry, and egg products as food additives, generally recognized as safe (GRAS) notices and pre-market notifications, and approved in letters conveying acceptability determinations

Food Safety and Inspection Service: *Establishment Responsibilities:*

☐ ***Responsibilities:***

- Establishments are expected to reassess their food safety system when changes, such as implementation of a new technology or ingredient occurs that could affect their hazard analysis or alter their Hazard Analysis and Critical Control Point (HACCP) plan (9 CFR 417.4 (a)(3))

Food Safety and Inspection Service:

Resources:

☐ **Resources:**

- Compliance Guides Index
http://www.fsis.usda.gov/Regulations/Compliance_Guides_Index/index.asp
- TPDS.protocols@usda.gov - Protocol Submission
- <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/New-Technologies> Provides a list of recent new technologies
- [FSIS Directive 7120.1](#). This directive provides an up-to-date list of substances that may be used in the production of meat, poultry, and egg products.
- FSIS regulation 9 CFR 424.21(c) provides a list of food ingredients that are approved for use in the production of meat, poultry and egg products

Food Safety and Inspection Service: *Questions:*

❑ *Questions ?:*

- ***Send questions to askFSIS- [askFSIS Submittal Instructions](#)***